

Message Text

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21

ORIGIN HEW-06

INFO OCT-01 AF-08 ARA-10 EUR-12 NEA-10 ISO-00 OES-06 /053 R

DRAFTED BY DHEW/FDA: JRWEINROTH, M.D.:CCK

APPROVED BY OES/APT/BMP: WJWALSH, III

DHEW/OIH: MACODDING

EUR/EX:CEREDMAN(INFO)

ARA/MEX:GFALK(INFO)

NEA/INS:BBROWN(INFO)

AF/S:FBCRUMP(INFO)

----- 042097

R 182247Z AUG 76

FM SECSTATE WASHDC

TO AMEMBASSY PARIS

AMEMBASSY BONN

AMEMBASSY ATHENS

AMEMBASSY NEW DELHI

AMEMBASSY TEL AVIV

AMEMBASSY ROME

AMEMBASSY MEXICO

AMEMBASSY THE HAGUE

AMEMBASSY OSLO

AMEMBASSY PRETORIA

AMEMBASSY MADRID

AMEMBASSY STOCKHOLM

AMEMBASSY LONDON

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E.O. 11652: N/A TAGS: EGEN, ETRD, EIND, TBIO, FR, GW, GR,

IN, IS, IT, MX, NC, NO, SF, SP, SW, UK

SUBJECT: FDA ADVISORY - DEFECTIVE HEMODIALYSIS MACHINES

RECALL T-136-6

1. FDA ADVISES OF THE FOLLOWING RECALL:

PRODUCT INVOLVED: DRAKE-WILLOCK HEMODIALYSIS MACHINES

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MODELS 4215, 4225 AND 4235. ALL SERIAL NUMBERS ARE UNDER

RECALL.

MANUFACTURER/RECALLING FIRM: DRAKE-WILLOCK, INC.
13520 SOUTH EAST PHEASANT COURT
PORTLAND, OREGON 97222

2. REASON FOR ADVISORY (RECALL) - THERE HAVE BEEN FAILURES OF THE AUDIO AND VISUAL ALARMS/SHUT DOWN SYSTEMS CONNECTED WITH THE CONDUCTIVITY AND BLOOD PRESSURE METERS DUE TO THE FAILURE OF THE ALARM TRIP RELAY PART NO. E-0096-00-00. ONE INJURY OCCURRED AT CINCINNATI GENERAL HOSPITAL, CINCINNATI, OHIO WHERE THE DIALYSIS MACHINE RAN OUT OF DIALYSATE AND THE ALARM AND SHUT DOWN SYSTEMS FAILED RESULTING IN THE

PATIENT SUFFERING HEART FAILURE, HOWEVER, PATIENT RECOVERED. DWS, INC., THE MANUFACTURER, REPORTED THAT OTHER COMPLAINTS OF FAILURES HAVE BEEN RECEIVED. THE FIRM HAS BEEN ABLE TO DETERMINE THAT THE FAILURES HAVE BEEN DUE TO DEFECTIVE RELAYS PROVIDED BY GUARDIAN ELECTRIC, CHICAGO, ILLINOIS. TWO PROBLEMS WITH THE RELAYS HAVE BEEN UNCOVERED. THE COIL INSULATION APPEARS TO BE VAPORIZING AND RECONDENSING ON THE CONTACT POINTS, ALLOWING NO CONTACT TO BE MADE WHEN THE RELAY TRIPS. THE SECOND PROBLEM IS CORROSION TO THE COIL PREVENTING THE RELAY FROM TRIPPING. THE FIRM ISSUED A RECALL LETTER AND TELETYPE MESSAGES REGARDING THE PROBLEMS. REPLACEMENT RELAYS, PART NO. E-0314-OA-00 HAVE BEEN SENT TO FOREIGN CONSIGNEES WITH INSTRUCTIONS FOR REPLACEMENT. THE SUPPLY OF NEW RELAYS TO THE FOREIGN CONSIGNEES WILL APPARENTLY BE HANDLED BY ONE GERMAN DISTRIBUTOR.

2. POSTS ARE REQUESTED TO CONTACT FOREIGN CONSIGNEES TO DETERMINE IF THEY HAVE RECEIVED RECALL LETTER AND REPLACEMENT RELAYS. ANY QUESTIONS FOREIGN CONSIGNEES MAY HAVE REGARDING THIS RECALL SHOULD BE DIRECTED TO THE FIRM.

3. FOREIGN CONSIGNEES AS FOLLOWS:

LA MAISON DU MEDECIN
300 RUE LON JOULIN
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TOULOUS 31076, FRANCE

DR. E. FRESENIUS KG
6380 BAD HOMBURG V.D.H.
GERMANY

DRAKE-WILLOCK GMBH
KAISER-FRIEDRICH-PROMENADE 30

6380 BAD HOMBURG
GERMANY

A. PSIMITIS
7 MONIS PETRAKI STR.
ATHENS 140, GREECE

MAZDA MEDICAL ELECTRONICS
6, DATTA MANDIR ROAD
BHANDUP, BOMBAY 400 078
INDIA

AMOS EQUIPMENT CO., LTD.
29 CARLEBACH ST., P P BOX 11017
TEL-AVIV 61110, ISRAEL

EUROSPITAL S.P.A.
VIA FLAVIA 122
34147 TRIESTE, ITALY

COMMERCIAL ULTRAMAR, S.A.
COLIMA NO. 4LL
MEXICO 7, D.F.

DREISSEN MEDISCHE APPARATENBOUW
MOLSHOEK 7 P.O. BOX 51
HELLEVOETSLUIS, NEDERLAND

VINGMED AS
HEGDEHAUGSUN 21B
POSTBOKS 7021 HOMANSBYEN
OLSO 3, NORWAY

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FREDERICK MARCUS
P O BOX 3039
CAPETOWN, SOUTH AFRICA

MARIE-NOELLE VACHER
BALMES, 245-247, 4.3
BARCELONA, SPAIN

ELMEDA AB
BOX 44019
100 73 STOCKHOLM 44, SWEDEN

AVON MEDICAL DIVISION
1649 PERSHORE ROAD, STIRCHLEY
BIRMINGHAM 30, ENGLAND KISSINGER

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NNN

Message Attributes

Automatic Decaptioning: X
Capture Date: 01 JAN 1994
Channel Indicators: n/a
Current Classification: UNCLASSIFIED
Concepts: MEDICAL EQUIPMENT, RECALLS
Control Number: n/a
Copy: SINGLE
Draft Date: 18 AUG 1976
Decaption Date: 01 JAN 1960
Decaption Note:
Disposition Action: n/a
Disposition Approved on Date:
Disposition Authority: n/a
Disposition Case Number: n/a
Disposition Comment:
Disposition Date: 01 JAN 1960
Disposition Event:
Disposition History: n/a
Disposition Reason:
Disposition Remarks:
Document Number: 1976STATE205675
Document Source: CORE
Document Unique ID: 00
Drafter: JRWEINROTH, M.D.:CCK
Enclosure: n/a
Executive Order: N/A
Errors: N/A
Film Number: D760317-1096
From: STATE
Handling Restrictions: n/a
Image Path:
ISecure: 1
Legacy Key: link1976/newtext/t19760841/aaaabjhx.tel
Line Count: 169
Locator: TEXT ON-LINE, ON MICROFILM
Office: ORIGIN HEW
Original Classification: UNCLASSIFIED
Original Handling Restrictions: n/a
Original Previous Classification: n/a
Original Previous Handling Restrictions: n/a
Page Count: 4
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Previous Classification: n/a
Previous Handling Restrictions: n/a
Reference: n/a
Review Action: RELEASED, APPROVED
Review Authority: CunninFX
Review Comment: n/a
Review Content Flags:
Review Date: 09 APR 2004
Review Event:
Review Exemptions: n/a
Review History: RELEASED <09 APR 2004 by ReddocGW>; APPROVED <03 JAN 2005 by CunninFX>
Review Markings:

Margaret P. Grafeld
Declassified/Released
US Department of State
EO Systematic Review
04 MAY 2006

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Review Release Event: n/a
Review Transfer Date:
Review Withdrawn Fields: n/a
Secure: OPEN
Status: NATIVE
Subject: FDA ADVISORY - DEFECTIVE HEMODIALYSIS MACHINES RECALL T-136-6
TAGS: EGEN, ETRD, EIND, TBIO, FR, GE, GR, IN, IS, IT, MX, NC, NO, SF, FDA, DRAKE-WILLOCK INC
To: PARIS
BONN
MULTIPLE
Type: TE
Markings: Margaret P. Grafeld Declassified/Released US Department of State EO Systematic Review 04 MAY 2006